

EC CERTIFICATE

Number: 3806368CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Staar Surgical AG

Hauptstrasse 104
CH 2560
Nidau
Switzerland

For the product category(ies):

Devices for Treatment/Correction of Ophthalmological Disorders

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents that form the basis of this certificate:

Certification Notice 3806368CN, initially dated March 25, 2011
Addendum, initially dated March 25, 2011

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation of the products concerned and the assessments performed are stated in the Certification Notice, which forms an integrative part of this certificate.

This certificate is valid until: **August 1, 2022**
Issued for the first time: March 25, 2011
Reissued: August 1, 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: **3806368CE01**

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Devices for Treatment/Correction of Ophthalmological Disorders

Issued to:

Staar Surgical AG

Hauptstrasse 104

CH 2560

Nidau

Switzerland

This certificate covers the following product(s):

Foldable Implantable Contact Lenses

Collamer Implantable Contact Lenses (Class III)

Initial date: March 25, 2011

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drs. G.J. Zoetbrood
Managing Director



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